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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,649	03/09/2001	Richard W. Compans	25-01	6596
23713	7590	05/05/2004	EXAMINER	
GREENLEE WINNER AND SULLIVAN P C			SHARAREH, SHAHNAM J	
5370 MANHATTAN CIRCLE			ART UNIT	
SUITE 201			PAPER NUMBER	
BOULDER, CO 80303			1617	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/803,649	COMPANS ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7-18 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5, 7-18, 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

1. Amendment filed on January 20, 2004 has been entered. Claims 1-2, 5, 7-18, 21-25 are pending. The new claim amendment has modified the scope of the claims, thus, necessitating a new ground of rejection. Any rejection that is not addressed in this Office Action is moot in view of the new ground of rejection.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-2, 5, 7, 12-16, 18, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anselem et al US Patent 5,716,637 in view of Glen et al US Patent 5,980,898.

Anselem teaches nanoemulsions comprising nanoparticles containing antigenic particles. (see abstract, example 1; claims 1-10). Anselem's compositions are used for inducing an immunogenic response via topical route. (see col 3, lines 36-39; 55-59; col 6, lines 55-56; claim 34). The emulsome particles of Anselem do not contain an adjuvant. (see figure 8, examples 6, 13, 19; claim 1). The antigenic particles of Anselem can include chemically or physically inactivated particles of a virus, such as Hepatitis B surface antigen, or bacteria such as Leishmania (see col 10, line 62-col 11, line 33). Thus, Anselem teaches topical immunization of a subject by using a composition comprising an antigenic nanoparticulate. Anselem does not explicitly provide the administration of his compositions on an unbroken surface.

Glenn et al. teaches a transcutaneous immunization formulation comprising antigen to unbroken skin and without perforation of the skin induces an immune response (see abstract). Glenn et al. further teaches that the antigen may be derived from a virus (see col. 3, lines 64-65, col. 5, lines 8-20). Glenn also teaches that an antigen may be in the form of an inactivated virus and be incorporated in a liposome before administration (see col. 4, lines 1-12, col 3, lines 55-58; col 11, line 40-col 12, line 66). Among the viruses that can be used in the practice of the invention Glenn teaches hepatitis, influenza, and measles (see col. 9).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to use Anselem's emulosmes containing an antigen on an unbroken surface of skin, as taught by Glenn. The ordinary skill in the art would have been motivated to do such application of Anselem's composition because as suggested by Anselem himself, topical delivery of such antigens are possible for inducing an immunogenic response and further, as suggested by Glenn, one of ordinary skill in the art would have had a reasonable expectation of success to provide a transcutaneous immunization through an unbroken skin surface.

3. Claims 2, 5, 7-18, 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anselem et al US Patent 5,716,637 in view of Glenn et al US Patent 5,980,898 and further in view of Fields et al.

The combination of the teachings of Anselem and Glenn were described above. Even though Anselem teaches chemical inactivation of his antigenic virus particles, neither Anselem or Glenn explicitly describe the use of Formalin for inactivation of the

particle, nor do they mention that influenza virus contains hemagglutinin(HA) and that such virus is a orthomovirus.

Fields et al. teaches that HA is the major antigen of influenza virus, a known orthomyxovirus (see page 1417-1418). Fields also teaches that semi-purified influenza virus subunit vaccines containing the HA surface antigens of the virus are less toxic than are activated whole virus vaccines (see page 475). Fields also teaches a method of inactivating viruses employing formalin (see page 475).

Accordingly, It would have been obvious to one of ordinary skill in the art at the time the invention was made to use influenza virus, an orthomyxovirus in Anselem's formulations as the antigenic particle, because the use of such viruses was envisioned by both Anselem and Glenn.

In addition, it would have been obvious to one of ordinary skill in the art at the time of invention to inactivate the viruses described by Anselem and Glen with Formalin or any widely known methods in the art, because as described by Fields, Formalin is frequently used to achieve such goal. Therefore, employing Formalin as the different methods of inactivating viruses would have been well within the purview of the Skilled Artisan and most likely a matter of design choice.

### ***Conclusion***


4. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RUSSELL TRAVERS  
PRIMARY EXAMINER